REMARKS

Interview Summary

Applicant's counsel conducted a personal interview with the Examiner of this application on March 14, 2005. The Examiner's Interview Summary accurately describes this interview. During the interview, Applicant's counsel provided paper copies of all materials cited in the Information Disclosure Statement ("IDS") of March 10, 2005. The interview did not involve a discussion of any office action or any pending claims. The Examiner and Applicant's counsel discussed the lawsuits referenced in the IDS.

Summary Of Office Action

In the Office Action of February 25, 2005, the Examiner commented on the IDS filed on July 30, 2003, and the Examiner rejected the pending claims.

Information Disclosure Statement

The Examiner asserted that the IDS filed on July 30, 2003 did not comply with 37 C.F.R. § 1.98(a)(2) because a copy of each non-patent document was not provided, and the Examiner stated that "the information referred to therein has not been considered." However, it appears that the Examiner did consider at least the cited U.S. and foreign patent references in the IDS of July 30, 2003; all of these references were marked off by the Examiner on a copy of the IDS and returned to Applicant's counsel. If this is not correct, the Examiner is requested to advise Applicant's counsel so that a replacement IDS can be provided. Regarding the non-patent references, Applicant believes that copies are not required under 37 C.F.R. § 1.98(d), but Applicant has nevertheless provided copies of the non-patent documents from the IDS of July 30, 2003 in the IDS filed herewith for the Examiner's convenience. Applicant respectfully requests consideration of these documents.

Response to Antecedent Basis Rejection

The Examiner rejected Claims 32-34, 61-63 and 93-94 under 35 U.S.C. § 112. Specifically, the Examiner asserted that "the orifice" recited in Claims 32-34, 61-63 and 93-94 lacks proper antecedent basis. However, each of these claim groups ultimately depend from independent Claims 25, 57 and 85, respectively. The independent claims all recite "an orifice," thereby providing the antecedent basis for "the orifice" recited in the rejected claims. See

Claim 25, line 17; Claim 57, line 16; and Claim 85, line 21. Thus, Applicant respectfully requests that the Examiner withdraw this rejection.

Response to Anticipation and Obviousness Rejections

The Examiner rejected all pending claims under 35 U.S.C. §§ 102 or 103 as anticipated or obvious over U.S. Patent No. 4,998,927 to Vaillancourt. The Examiner cited the connector illustrated in Figures 3 and 4 of the Vaillancourt patent to support the rejections of all pending claims. This connector is reproduced below:

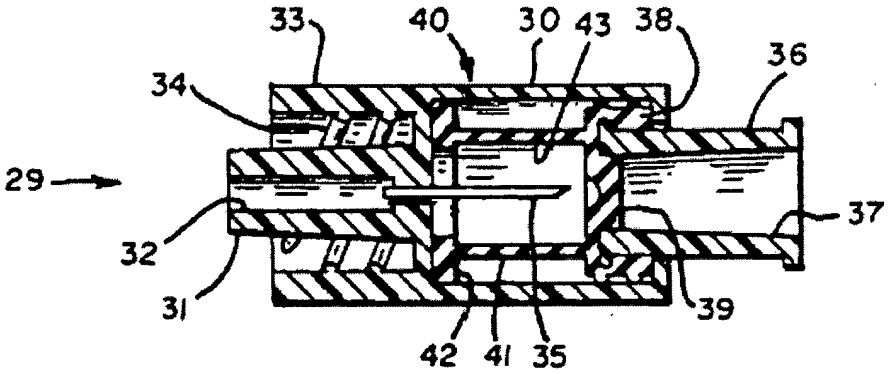

FIG. 3

The Vaillancourt connector includes a housing 30 containing a hollow needle 35. The needle 35 is positioned within a chamber 43 formed by a collapsible cylindrical wall 41 and a rubber septum 39. The rubber septum 39 is attached to an annular sealing ring 38. An adaptor 36 is attached to the rubber septum 39 and the annular sealing ring 38. A first end of the adaptor 36 is position within the housing 30 and a second end of the adaptor 36 is positioned outside of the housing. As explained below, the Vaillancourt connector fails to disclose or suggest many limitations in the pending claims, and thus cannot render the claims unpatentable.

No Flush Proximal End On Rubber Septum

The end of the rubber septum 39 and the sealing ring 38 of Vaillancourt are both inset within the housing 30. It would be difficult to effectively swab antiseptic across these surfaces to cleanse them, and thus contaminants and debris could accumulate inside the adaptor 36 and/or on the rubber septum 39. Vaillancourt attempts to mitigate this problem by proposing that antiseptic material could be wiped on the syringe that is inserted into the connector. See col. 4, lines 67 - col. 5, line 2. However, the contact between the connector and the cleansed syringe

would not ensure that the connector itself is also cleansed. Vaillancourt further acknowledges that the disclosed connector is prone to collect contaminates by suggesting that a "cap" may be "placed over the female adaptor to maintain a sterile condition." Col. 2, lines 33-34; see also col. 4, lines 61-63.[1]

In contrast, pending Claims 25 and 57 (and all of their corresponding dependent claims) recite that "the proximal end of the flexible element" is "generally flush with the proximal end of the housing." Claim 25, lines 19-20; Claim 57, line 18. Claim 25 further recites that this configuration "presents an impediment to entry of bacteria into the fluid pathway without requiring a covering for the housing." Claim 25, lines 20-22. The specification explains some of the advantages of this structure as follows:

> ...after assembly, the top surface 40b of the seal cap 40 is essentially flush with the lip 25, so that the lip 25 and seal cap 40 can be swabbed with alcohol or other disinfectant without leakage of disinfectant into the valve 10. It is important that the surface 40b be exposed so that it may be swabbed with a disinfectant.
>
> * * *
>
> . . .a cover cap. . .is not needed to maintain sterility since the seal 36 may be swabbed with a disinfectant after each use.

App. at ¶¶ 48, 54. Unlike the inventions recited in the pending claims, the Vaillancourt connector cannot be cleansed by wiping a swab across the end of the housing 30 because the rubber septum 39 is inset within the housing 30 rather than being "generally flush" with the proximal end of the housing. Thus, the Vaillancourt connector poses a greater risk of contamination. For at least these reasons, Vaillancourt neither anticipates nor renders obvious pending Claims 25-84.

No Close Radial Proximity Between Base Of Needle And Collapsible Wall

In the Vaillancourt connector, the base of the needle 35 is spaced a substantial distance from the collapsible wall 41. See Figs. 3 and 4; see also col. 6, lines 35-36. Consequently, the

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[1] In describing previous attempts by others to solve these problems, the present application explained some of the drawbacks of using a cap to maintain sterile conditions. Applicant observed that "[f]requently these caps are lost, or simply not used because they are not readily available when needed." App. at ¶ 6.

needle 35 does not provide any support for the collapsible wall 41 to assist in directing the movement of the collapsible wall 41 in a consistent and predictable manner. See Claims 27, 28. Moreover, the substantial spacing between the base of the needle 35 and the collapsible wall 41 could cause the Vaillancourt connector to retain a significant proportion of the fluid volume within the chamber 43 between the sides of the needle 35 and the collapsible wall 31.

In contrast, all of the pending claims include one of the following phrases: (i) "the distal end of the flexible element is positioned in *close radial proximity* with a distal section of the spike" (Claims 25-56, emphasis added); (ii) "the distal end of the flexible element is positioned in *close radial proximity* with a distal section of the tube" (Claims 57-84, emphasis added); and (iii) "the distal end of the flexible element is positioned in *close radial proximity* with a distal section of the rigid element" (Claims 85-119, emphasis added). The Vaillancourt connector neither discloses nor suggests these claim limitations, and thus cannot anticipate or render obvious the pending claims.

No Orifice On The Rubber Septum

The Vaillancourt patent explains that the rubber septum 39 includes "a reduced portion opposite the distal end of the needle 35 for *piercing* thereby." Col. 5, lines 25-26 (emphasis added). The rubber septum 39 does not include an "orifice" to allow fluid to flow through the septum 39 without being pierced by the needle 35.

In contrast, the pending claims include a flexible element with an orifice at the proximal end to facilitate or permit fluid flow. See Claim 25, line 17; Claim 57, lines 16-17; Claim 85, line 21 (also included in all dependent claims by incorporation). Thus, in the pending claims, the spike, tube, or rigid element need not pierce or puncture the flexible element, and Vaillancourt does not render these claims unpatentable.

No Horizontal Grooves In The Collapsible Wall

Claims 57 and 85 (and all of their dependent claims) recite that the flexible element includes "a series of closely spaced, substantially horizontal grooves to facilitate axial compression" of the flexible element.

In contrast, the exterior and interior surfaces of the collapsible wall 41 of the Vaillancourt connector are smooth. During compression of the Vaillancourt connector, the points where the collapsible wall 41 buckles (as shown in Figure 4) may be somewhat random and

unpredictable, and the collapsible wall 41 may require a greater amount of force to compress. Because Vaillancourt neither discloses nor suggests the use of grooves to facilitate compression, it does not anticipate or render obvious Claims 57-119.

No Larger Third Internal Diameter Within Housing

In the Vaillancourt connector, the portion of the housing 30 that contains the collapsible wall 41 and rubber septum 39 has the same diameter along its entire length. The Examiner correctly observed that "Vaillancourt does not disclose a third cross section width" across the housing 30 as recited in Claims 35-37. Similar claim language is also included in Claims 64-66, 90, 96 and 97. The Examiner stated that, in the absence of any functional reason for this limitation, it would be considered an ornamental design choice. See Office Action at 3-4. However, this claim limitation *does* have functional purposes. For example, in the embodiment illustrated in Figure 19 of Applicant's specification, the region with a third, larger cross-sectional width provides additional volume outside of the fluid flow path into which the flexible element can expand when compressed, see App. at ¶ 71, while allowing for minimized volume in other regions of the housing. The larger cross section width in the third region can alternatively provide other advantages. Thus, this claim limitation is not an ornamental design choice and the rejection of these claims should be withdrawn.

No Plastic Needle

Claims 42, 57-84 and 102 recite that plastic is used to form the spike, tube, or rigid element, respectively. In contrast, the Vaillancourt patent discloses a needle 35. The only material for any needle disclosed in the Vaillancourt patent is "metal." See col. 4, line 8. The benefits of using a plastic spike, tube, or rigid element are numerous. For example, plastic is typically less expensive and the manufacturing process may be simplified. Because Vaillancourt neither discloses nor suggests the limitations of Claims 42, 57-84 and 102, these claims are neither anticipated nor rendered obvious.

No Disclosure Of Lengths

The Vaillancourt patent does not appear to provide any length measurements at all, and Vaillancourt certainly does not disclose the distance between the proximal end of the housing and the tip of the needle. In contrast, Claims 46-47, 74-75 and 106-107 each recite specific distances between the proximal end of either the housing and the spike, tube, or rigid element,

respectively. The Examiner argues that the claimed distances are obvious because the distance from the spike to the end of the housing must be within a certain range to open the valve. However, this argument does not acknowledge that: (i) the length of either the spike, tube, or rigid element, respectively, can also vary over a wide range, and (ii) a valve with an orifice in the proximal end of the flexible element (as recited in all pending claims) does not require that either the spike, tube, or rigid element, respectively, open the valve. Thus, Vaillancourt fails to disclose or suggest the limitations or Claims 46-47, 74-75 and 106-107, and hence these claims are not anticipated or obvious.

Conclusion

Applicant has identified multiple limitations in all of the pending claims that are neither disclosed nor suggested by the Vaillancourt patent.[2] Thus, the pending claims are not anticipated or rendered obvious by Vaillancourt. Applicant therefore requests that the Examiner allow this application to proceed to issuance.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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[2] Further analysis may also reveal additional differences between the pending claims and the cited prior art.